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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,924	12/19/2001	Yanagita Toshihiko	YAM 2 0013	8207

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EXAMINER

SNEDDEN, SHERIDAN

ART UNIT	PAPER NUMBER
1653	6

DATE MAILED: 03/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Offic Action Summary	Application No.	Applicant(s)
	10/018,924	TOSHIHIKO, YANAGITA
Examiner	Art Unit	
Sheridan K Snedden	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-14 is/are pending in the application.
 - 4a) Of the above claim(s) none is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-14 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.

- 4) Interview Summary (PTO-413) Paper No(s) _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____

DETAILED ACTION

Specification

1. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825. Specifically, Figure 4 and description thereto, fail to reference the sequence by SEQ ID NO.

Applicant is reminded of the following:

§1.821 Nucleotide and/or amino acid sequence disclosures in patent applications.

(a) Nucleotide and/or amino acid sequences as used in § 1.821 through 1.825 are interpreted to mean an **unbranched sequence of four or more amino acids or an unbranched sequence of ten or more nucleotides**. Branched sequences are specifically excluded from this definition. Sequences with fewer than four specifically defined nucleotides or amino acids are specifically excluded from this section.

(d) Where the **description or claims** of a patent application discuss a sequence that is set forth in the "Sequence Listing" in accordance with paragraph (c) of this section, **reference must be made to the sequence by use of the sequence identifier, preceded by "SEQ ID NO:"** in the text of the description or claims, even if the sequence is also embedded in the text of the description or claims of the patent application.

Full compliance with the sequence rules is required in response to this Office action. A complete response to this Office action must include both compliance with the sequence rules and a response to the issues set forth below. Failure to fully comply with both of these requirements in the time period set forth in this Office action will be held to be non-responsive.

Claim Rejections - 35 USC § 101

2. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claim 1 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Adrenomedullin as claimed, has an amino acid sequence duplicative of

that of the protein and possesses the biological functional properties of the naturally accruing Adrenomedullin protein and therefore does not constitute patentable subject matter. The current recitation of "composition for promoting passive extension of bladder smooth muscle," is an intended use limitation that does not alter *per se* the composition.

4. Additionally, claims 13 and 14 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966). Without the recitation of the steps to practice the method, the claims are incomplete.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4-7, 13 and 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 4-7 refer to peptides comprising fragments of SEQ ID NO: 2 also having one or several amino acids deleted, substituted or added in the amino acid sequence. However, it is unclear as to the scope to the claimed invention. Are all amino acids of SEQ ID NO: 2 deleted or substituted? Which amino acids and in what order are added to the fragments as claimed of SEQ ID NO: 2?

Claims 13 and 14 provide for the use of a composition comprising adrenomedullin, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Kitamura *et al.* (US Patent 5,910,416). Kitamura *et al.* adrenomedullin as a novel hypotensive peptide. Kitamura *et al.* teach the intravenous administration of a composition comprising adrenomedullin (see figure 3; regarding claim 1). The composition of Kitamura *et al.* comprises the peptide having the amino acid sequence from Ser13 to Tyr52, Tyr1 to Tyr52, Ala(-73) to Tyr52, and Met(-94) to Leu91 of SEQ ID NO: 2 (regarding claims 4-7). In one embodiment of the above peptide, the carboxyl terminus of the peptide is amidated (see column 1, lines 66 and 67; regarding claim 8). In one embodiment of the above peptide, Gly is attached to the carboxyl terminus of the N-terminal peptide of proadrenomedullin (see column 2, lines 1 and 2). In one embodiment of the above peptide, Cys in the 16 position and Cys in the 21 position of SEQ ID No. 1 are linked by a disulfide bond, which may be substitutes with a –CH2—CH2— bond (see column 2, lines 8-13; regarding claims 10-12). Claims 2 and 3 further limit the use of the

composition or the patient or disorder the composition is intended to treat and not the composition itself, and are thus included in this rejection as the claims are dependent on claim 1. Thus, the reference anticipates the invention s recited in claims 1-12.

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan K Snedden whose telephone number is (703) 305-4843. The examiner can normally be reached on Monday - Friday, 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone number for regular communications to the organization where this application or proceeding is assigned is (703) 746-3975.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



SKS
March 23, 2003



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